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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,501	12/13/2001	Charles F. Streckfus	4856-CIP	8069

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EXAMINER	
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ART UNIT	PAPER NUMBER
1642	6

DATE MAILED: 04/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,501	STRECKFUS ET AL.	
	Examiner	Art Unit	
	Jennifer E Hunt	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 1-20 are pending in the application and considered herein.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,294,349. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth below.

3a. Claims 1-9 of the instant application are not patentably distinct from claims 1-6 of US Patent 6,294,349 because both sets of claims are drawn to a method of using salivary secretions to diagnose carcinoma of the breast in a human test subject by providing a salivary secretion specimen from the subject, and determining the concentration of cancer antigen 15-3, tumor suppressor protein 53, or oncogene

c-erbb-2 and combinations thereof, and using the concentration of these biomarkers to diagnose the human subject.

The claims differ in that the claims of 6,294,349 fail to recite that the diagnosis is a differential diagnosis, and the claims of 6,294,349 also fail to recite that the biomarker panel includes at least one of cancer antigen 15-3, tumor suppressor oncogene protein 53, and oncogene c-erbB-2.

It would be an intrinsic property of the method that the diagnosis is differential. The method utilizes the same steps and produces the same diagnosis; that it would differentiate the diagnosis does not impart a new quality to the method. Further, it would be obvious to include at least one of cancer antigen 15-3, tumor suppressor oncogene protein 53, and oncogene c-erbB-2 in the biomarker panel, because these are the specific antigens to be tested, as recited by the claims in the instant application, thus it would be necessary to include them as part of the panel in order to provide a control, which would be necessary to successfully diagnose breast carcinoma.

Thus it would have been obvious to use the instant method as a differential diagnosis, and to use at least one of cancer antigen 15-3, tumor suppressor oncogene protein 53, and oncogene c-erbB-2 in the biomarker panel and one would have been motivated to do so because these would be intrinsic properties of the instant method and necessary to be diagnostic, as set forth above.

3b. Claims 10-14 of the instant application are not patentably distinct from claims 7-11 of US Patent 6,294,349 because both methods are drawn to measuring biomarkers in salivary secretions post-surgery to determine disease state.

The claims differ in that the claims of 6,294,349 are specific for monitoring the inhibition of breast tumor growth, while the instant application recites monitoring the inhibition of tumor growth (not specifically breast), and because the claims of 6,294,349 include "total protein" as part of the panel of tested proteins.

With regard to the omission of total protein from the reference panel, the panel would still contain sufficient biomarkers to be diagnostic because cancer antigen 15-3, tumor suppressor protein 53, oncogene c-erbb-2 are themselves known to be diagnostic for breast cancer, and thus total protein level is not essential for such diagnosis.

It would be obvious to one of skill in the art to modify the claims of 6,294,349 by monitoring tumor growth in general, provided that the tumor growth was characterized by overexpression of cancer antigen 15-3, tumor suppressor protein 53, oncogene c-erbb-2, or by omitting total protein level tests, and one would have been motivated to do so because the instant assay could be used to measure any disease process characterized by overexpression of cancer antigen 15-3, tumor suppressor protein 53, or oncogene c-erbb-2 and further because total protein tests were not essential to the diagnosis of breast cancer.

3c. Claims 15-20 of the instant application are not patentably distinct from claims 12-17 of US Patent 6,294,349 because both sets of claims are drawn to a

method of using salivary secretions to diagnose carcinoma of the breast in a human test subject by providing a salivary secretion specimen from the subject, and determining the concentration of cancer antigen 15-3, tumor suppressor protein 53, or oncogene c-erbb-2 and combinations thereof, and using the concentration of these biomarkers to diagnose the human subject.

The claims differ in that the claims of 6,294,349 fail to recite that the diagnosis is determined eliminating the effect of the estrous cycle on the protein concentrations.

The method of 6,294,349 functions whether the effects of the estrous cycle on the protein concentrations have been eliminated or not. Thus this step is not necessary for the method to be effective.

Thus it would have been obvious to use the instant method absent the elimination of the effect of the estrous cycle on the protein concentrations one would have been motivated to do so because this step is not a necessary step for diagnosis and would eliminate a method step without decreasing diagnostic efficacy.

4. Claims 1-6, 9-11, and 13-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 21-29 of copending Application No. 09/962,477. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only differences in the claims would be obvious variations, as set forth below:

4a. Claims 1-6, 9, and 15-20 of the instant application are not patentably distinct from claims 21-25 of copending Application No. 09/962,477 because both sets of claims are drawn to a method of using salivary secretions to diagnose carcinoma of the breast in a human test subject by providing a salivary secretion specimen from the subject, and determining the concentration of cancer antigen 15-3, tumor suppressor protein 53, oncogene c-erbb-2 and combinations thereof, and using the concentration of these biomarkers to diagnose the human subject.

The claims differ in that the claims of copending Application No. 09/962,477 recite the additional limitation that the method further includes mammography.

It would have been obvious combine the instantly claimed assay with a mammography, because mammography is an established breast cancer screening method and combining two tests known for the same purpose would provide additional information useful to a physician in providing an accurate diagnosis and further because "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form the third composition that is to be used for the very same purpose: idea of combining them flows logically from their having been taught individually in the prior art." In re Kerkhoven (205 USPQ 1069, CCPA 1980).

4b. Claims 10-11 and 13-14 of the instant application are not patentably distinct from claims 26-29 of copending Application No. 09/962,477 because both methods are drawn to measuring biomarkers in salivary secretions post-treatment to determine disease state.

The claims differ in that the claims of the instant application recite that the test is "post-operative", while the claims of copending Application No. 09/962,477 recite that the test is "post treatment".

A method of monitoring cancer status which could be used post-operatively, could also be used after any form of treatment, because the test is directed to monitoring of cancer status, and would function throughout all stages of the disease and treatment.

It would be obvious to one of skill in the art to modify the claims the instant application by monitoring cancer post-treatment, and one would have been motivated to do so because post-treatment tests allow monitoring of cancer progression or regression throughout a patient's disease.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 10-14 are indefinite because the preamble does not match the correlation step, and thus the method is incomplete. See MPEP § 2172.01. While all of the technical details of the method need not be recited, the claims should include enough information to clearly and accurately describe the invention and how it is practiced.

The minimum requirement for method steps should at least include a contacting step in which the reaction of the sample with the reagents necessary for the assay is recited, a detection step in which the reaction steps are quantified or visualized and a correlation step describing how the results of the assay allow the determination.

In the instant case, the method is drawn to "monitoring inhibition of tumor growth," while the correlation step refers to "determining post-operative inhibition of breast malignancy." Determining inhibition of breast malignancy would be insufficient to provide a determination of inhibition of tumor growth in general.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Streckfus et al., The presence of CA 15-3, c-erbB-2, cathepsin-D, EGFR, WAF1, and p53 in saliva among women with benign and malignant breast disease., The Journal of Dental Research, Volume 77, page 285, Abstract# 1437, January 1998.

Streckfus et al. teaches the use of CA 15-3, c-erbB-2, and p53 as salivary biomarkers for cancer of the breast. This method includes generation of a reference panel and individual panel of biomarkers, with individual panel being compared to the reference as a method of the diagnosis. Streckfus et al. teaches that the reference panel is compiled from malignant tumor, benign tumor, and control group populations. The method includes determination of the concentrations of these biomarkers. Streckfus et al. further teaches that p53 levels are about 25% lower for subjects having malignant breast carcinoma. Streckfus et al. differs from the instant claims in that Streckfus et al. tests whole saliva, while the instant claims are drawn to testing salivary secretions, which is saliva, absent a cellular component.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E Hunt whose telephone number is (703) 308-7548. The examiner can normally be reached on Monday-Friday, 6-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Jennifer E Hunt
Examiner
Art Unit 1642

jeh
March 27, 2002

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